

6.4 *Special Precautions for Storage*

Do not store above 25°C.

6.5 *Nature and Contents of Container*

a. *35g aluminium tube with re-usable applicator*

An aluminium tube containing 35g of gel with a re-usable LDPE applicator designed to deliver 2.5g.

b. *Pre-filled single use applicator*

A single use one piece applicator, white, with a tear off cap, made of white polyethylene.

Each applicator contains 5.9g of gel and will deliver 2.5g of gel. Each applicator is individually wrapped and sealed in a foil overwrap and packed in cardboard boxes containing 3, 6 or 12 applicators each.

6.6 *Instructions for Use/Handling*

None.

6.7 *Name or style and permanent address or registered place of business of the holder of the Marketing authorisation*

COLUMBIA LABORATORIES (UK) LTD

Titmore Court, Titmore Green, Little Wymondley, Hitchin, Herts SG4 7XJ, England.

7. Classification

Medical Device CE0120. Class IIa device under Annexe IX, rule 5 Medical Devices Directives 93/42/EEC.

8. Date of Classification

15 September 2002.

9. Date of (Partial) Revision of the Text

January 2003.



SUMMARY OF PRODUCT CHARACTERISTICS

REPLENSMD

- 1. Name of the Medicinal Product** ReplensMD®
- 2. Qualitative and Quantitative Composition**
- | | Quantity | %w/w |
|---------------------------|--------------|-------|
| <i>Active ingredients</i> | mg/2.5g dose | |
| Purified Water Ph. Eur. | 1970.5 | 78.82 |

3. Pharmaceutical Form

Vaginal Gel. ReplensMD is a soft white gel.

4. Clinical Particulars

4.1 Therapeutic Indications

Symptomatic relief of vaginal atrophy, dryness, itching, irritation & discomfort.

ReplensMD is not intended for use as a substitute for hormonal replacement therapy, but it may be given concomitantly for the symptomatic relief of vaginal atrophy.

4.2 Posology and Method of Administration

Intravaginal application.

Adults: One application (2.5 g) to be inserted into the vagina three times a week, preferably in the morning.

Maintenance therapy can be achieved with a three times weekly application.

Elderly: As for adults.

Children: Do not use in children.

a. 35g aluminium tube with re-usable applicator

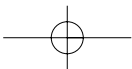
1. Remove cap from ReplensMD tube. Break seal on tube opening by puncturing it with opposite end of cap. Screw on the open end of applicator to tube.

2. Pull end of applicator to open barrel. Gently squeeze opposite end of tube, pushing gel into open barrel of applicator.

3. When the barrel is full, unscrew applicator from tube. After each use, replace cap and roll up the tube from the bottom.

4. The applicator may be inserted while you are in a sitting position or when lying on your back with knees bent. Gently insert the open end of the filled applicator into the vagina as deeply as it will go comfortably. Holding the applicator in place with thumb and middle finger, press the plunger until it stops. Withdraw the applicator.

5. After use, pull the plunger all the way out of the barrel. Wash both parts of the applicator in



warm, soapy water. Rinse thoroughly and dry. To reassemble, gently push the plunger back into the barrel as far as it will go.

6. ReplensMD coats the vaginal mucosa to provide long-lasting moisturisation

b. Pre-filled single use applicator

ReplensMD is applied directly from the specially designed sealed applicator into the vagina.

Remove the applicator from the sealed wrapper. DO NOT remove the twist-off cap at this time.

1. Grip the applicator firmly by the thick end. Shake down like a thermometer to ensure that the contents are at the thin end.

2. Twist off the tab and discard.

3. The applicator may be inserted while you are in a sitting position or when lying on your back with the knees bent. Gently insert the thin end of the applicator well into the vagina.

4. Press the thick end of the applicator firmly to deposit the gel. Remove the applicator and discard in a waste container.

5. ReplensMD coats the vaginal mucosa to provide long-lasting moisturisation

4.3 *Contra-indications*

Known allergy to any of the excipients.

4.4 *Special Warnings and Precautions for Use*

If irritation persists or develops, consult the doctor.

4.5 *Interactions with other Medicaments and other Forms of Interactions*

No specific interactions have been studied. *In vitro* tests did not demonstrate any spermicidal effect of ReplensMD on human spermatozoa.

4.6 *Pregnancy and Lactation*

Do not use in pregnancy or during the early post-partum period.

4.7 *Effects on Ability to Drive and Use Machines*

None.

4.8 *Undesirable Effects*

Leakage of the gel and infrequently, a white residue.

4.9 *Overdose*

ReplensMD is non-toxic and overdosage is not anticipated as each dose is applied through an individual applicator.



5. Pharmacological Properties

5.1 Pharmacodynamic Properties

The action of ReplensMD is to moisturise the vaginal epithelium. Polycarbophil attaches to mucin in the vaginal vault and to the vaginal epithelium. Polycarbophil is hydrophilic and provides a moist film over the vaginal wall hydrating the underlying mucosa.

5.2 Pharmacokinetic Properties

The active ingredient is water. ReplensMD has a local moisturising action on the vaginal mucosa thus pharmacokinetic studies are not appropriate.

5.3 Preclinical Safety Data

ReplensMD was determined not to have dermal or vaginal irritancy effects in Rabbits and to be non-allergenic in Guinea-Pigs.

Minimal ocular irritation was observed in Rabbits.

Chronic toxicity, mutagenicity, carcinogenicity and reproduction studies have not been undertaken with ReplensMD.

ReplensMD does not affect the motility or the viability of spermatozoa.

6. Pharmaceutical Particulars

6.1 List of excipients

a. 35g aluminium tube with re-usable applicator

Polycarbophil, glycerol, light liquid paraffin, hydrogenated palm oil glycerides, carbomer 974P, sorbic acid, methylparaben, sodium hydroxide.

b. Pre-filled single use applicator

Polycarbophil, glycerol, light liquid paraffin, hydrogenated palm oil glycerides, carbomer 974P, sorbic acid, sodium hydroxide.

6.2 Incompatibilities

None known.

6.3 Shelf Life

36 months.

